

REMARKS

A. Background

Claims 13-27 were pending in the application at the time of the Advisory Action. Claims 13-27 were rejected in the Office Action and again rejected in the Advisory Action as being obvious over cited art. By this response Applicant has amended claims 13 and 20 and has added new claims 28 and 29. As such, claims 13-29 are again presented for the Examiner's consideration in light of the following remarks.

B. Proposed Claim Amendments

Applicant has herein amended claims 13 and 20 and has added new claims 28 and 29. The amendments have been made to clarify that the gas temperature, the gas concentration, and the condensation are measured and that the condensation can be measure by a sensor within the enclosure. These amendments are supported at least at page 8, lines 13-16 and 23-24 of the specification and Figure 1 as originally filed. In view of the foregoing, applicant submits that the amendments to the claims do not introduce new matter and entry thereof is respectfully requested.

C. Rejection on the Merits

The Advisory Action rejected the arguments made in the previous response to the outstanding Office Action and thus maintains that claims 13-27 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Number 4,952,370 to Cummings et al. ("Cummings") in view of U.S. Patent Number 5,173,258 to Childers ("Childers '258") and U.S. Patent Number 5,906,794 to

Childers (“Childers ‘794”), as detailed in the Office Action dated January 9, 2006. Applicant respectfully traverses this rejection.

To control the amount of hydrogen peroxide concentration within the Cummings enclosure, the Office Action asserts that Cummings teaches “[t]he concentration, temperature and pressure parameters within the enclosure are monitored and injection of the steam/hydrogen peroxide is actuated in response thereto.” Assuming, *arguendo*, that this is true, Cummings still does not teach

the gas temperature in or exiting the enclosure or entering the preparation region, decontaminant gas concentration in or exiting the enclosure or entering the preparation region and **condensation of the decontaminant gas on the surfaces of the enclosure are measured** and the **dispensing of the mixture of decontaminant gas and water vapour into the gas in the preparation region is controlled in response to the levels determined by said measuring**,

as recited in amended claim 13, or

means (17, 18) are provided for measuring the condensation of the decontaminant gas on the surfaces of the enclosure and means (19) are provided for controlling the dispensing of the mixture of decontaminant gas and water vapour into the gas in the preparation region **in response to the levels determined by said measuring** to provide a predetermined level of condensation of the mixture of decontaminant gas and water vapour in the enclosure,

as recited in amended claim 20.

Specifically, while Cummings may arguably measure temperature and concentration parameters, as asserted by the Office Action, Cummings does not disclose or suggest measuring the condensation of the decontaminate gas on the surfaces of the enclosure nor does it disclose or suggest means for such measuring. Indeed, neither the Office Action nor the Advisory Action assert that Cummings measures condensation or has corresponding means. Furthermore, because Cummings does not measure the condensation on the surfaces of the enclosure and does not have corresponding mean, Cummings cannot control dispensing of the mixture of decontaminant gas and

water vapour into the gas based on such “measuring” as is required by claim 13 nor does it disclose means for controlling such dispensing as recited in claim 20.

As noted in the previous response, the Office Action points to Childers ‘258 and Childers ‘794 to cure the deficiency of Cummings of not continuously recirculating the gas. Initially, applicant asserts that even if, *arguendo*, the alleged gas recirculation means of Childers ‘258 and Childers ‘794 were combined with the Cummings device in the purportedly obvious manner asserted by the Office Action, the combination would still not cure the deficiencies of Cummings, described above. Specifically, applicant submits that Childers ‘258 and Childers ‘794 do not disclose or suggest a method of sterilizing a sealed enclosure in which “**the ... condensation of the decontaminant gas on the surfaces of the enclosure [is] measured,**” as recited in claim 13, and do not disclose or suggest “**means ... for measuring the condensation of the decontaminant gas on the surfaces of the enclosure,**” as recited in claim 20.

The Advisory Action states that “Childers ... specifically monitors the relative humidity for such saturations levels, as well as the sterilant concentration, temperature and pressure within the system in order to control the continued injection of hydrogen peroxide.” Note that, as in Cummings, no mention is made of actually measuring condensation on the surfaces of the enclosure. Applicant submits that this is because Cummings, Childers ‘258, and Childers ‘794 all fail to disclose the claimed measuring of condensation or the means to do so. As such, even assuming, *arguendo*, that the Cummings device was modified by Childers ‘258 and/or Childers ‘794 in the purportedly obvious manner asserted by the Office Action, applicant asserts that the combination would still not produce the inventions as recited in claims 13 and 20.

Furthermore, for at least the same reasons as discussed above, applicant also submits that the cited prior art does not disclose or suggest “wherein the condensation of the decontaminant gas on the surfaces of the enclosure is measured by a condensation sensor at least partially disposed within the enclosure,” as recited in new claim 28 and does not disclose or suggest “wherein the means for measuring the condensation of the decontaminant gas on the surfaces of the enclosure comprises a condensation sensor at least partially disposed within the enclosure,” as recited in new claim 29.

As discussed in the prior response, it has been established that faster and more reliable surface decontamination may be achieved if micro condensation is encouraged and controlled. Micro condensation is established and controlled in part by the ability to directly measure the condensation. See page 3, lines 30-35 and page 7, lines 21-27 of the present application as originally filed. Thus, the invention recited in claims 13 and 20 has unique advantages over the cited prior art.

Finally, applicant also asserts that a proper motivation to combine the teachings of Cummings with Childers ‘258 and Childers ‘794 has not been established. The prior art must teach or suggest making a modification to the prior art in order to render a claimed invention obvious. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). In other words, one must be **motivated** by the prior art to make the modification necessary to arrive at the present invention. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). Absent such motivation, a rejection based on a combination of references is unsupported and any rejection based on such a combination must be withdrawn. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

As to the motivation for the purportedly obvious combination, the Office Action has asserted that it would have been obvious to combine the sterilization system of Cummings with recirculation methods of Childers '258 and Childers '794 "because it would ... minimize the environment affects on system performance, thereby minimizing equipment requirements and making operation of the system easier." (*Emphasis added.*) Applicant notes at the outset that "minimize the environment affects on system performance," "minimizing equipment requirements," and "making operation of the system easier" are relative terms whose definition is known only to the Examiner. For example, it is not apparent what reference point(s) the Examiner is using as a basis to assert and/or establish that such minimization or easiness would be achieved. Accordingly, the ability of the Applicant to respond to the allegations made by the Office Action is at least somewhat compromised.

Additionally, the Office Action has failed to establish that the Cummings system suffers from such shortcomings as could, or would, be remedied through the use of the Childers '258 and/or Childers '794 disclosures. In the absence of any evidence that the Cummings system is somehow deficient in terms of environment affects on system performance, equipment requirements, or ease of operation, accurate test results or needs enhancement, Applicant submits that the Office Action has failed to establish the existence of the requisite motivation to make the purportedly obvious combination.

In view of the foregoing, applicant submits that both the Office Action and the Advisory Action have failed to establish a *prima facie* case of obviousness regarding claims 13 and 20 because the requisite motivation to combine Cummings with Childers '258 and/or Childers '794 is lacking and because the alleged combination does not teach or suggest all the claim limitations of claims 13 and

20. Accordingly, Applicant respectfully requests that the obviousness rejection with respect to claims 13 and 20 be withdrawn.

Claims 14-19 and 21-27 each depend from claim 13 or 20, and thus incorporate the limitations thereof. As such, applicant submits that claims 14-19 and 21-27 are distinguished over the cited art for at least the same reasons as discussed above with regard to claims 13 and 20. Accordingly, Applicant respectfully requests that the obviousness rejection with respect to claims 14-19 and 21-27 also be withdrawn.

Applicant submits that many if not all of the dependent claims may also be independently distinguishable over the proposed combination. For example, claims 26 and 27 recite “heating the gas” (in claim 26), and “means for heating the gas” (in claim 27) “in said preparation region prior to circulation through the enclosure.” Cummings does not disclose any heating of or means for heating water vapor or hydrogen peroxide vapor before injection into the enclosure. In fact, Cummings teaches against such heating. Specifically, if the mixture was heated before injection into the enclosure, it would necessarily impart at least some of the heat to the enclosure. Yet one of the stated objectives of Cummings is to maintain the cool temperature of the enclosure during sterilization. See col. 2, lines 28-38. To achieve this objective, the vacuum is used so that the hydrogen peroxide and water can be vaporized without applying heat. Thus, Cummings does not disclose heating of the gas or means for heating the gas since such methods and structures are in direct contrast to the intended function and operation of the system of Cummings. As such, applicant also submits that claims 26 and 27 are independently allowable over the cited art.

No other objections or rejections are set forth in the Office Action or the Advisory Action.

D. Conclusion

In view of the foregoing, applicant respectfully requests the Examiner's reconsideration and allowance of claims 13-29 as presented herein.

In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Dated this 26 day of June 2006.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Dana L. Tangren", with a long horizontal flourish extending to the right.

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